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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,918	10/11/2005	Jie Mi	AVIOR-09657	6412

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EXAMINER	
HAMA, JOANNE	
ART UNIT	PAPER NUMBER
1632	
MAIL DATE	DELIVERY MODE
04/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,918	MI ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1 in the reply filed on January 30, 2008 is acknowledged. The traversal is on the ground(s) that the claims of Groups 1-3 have unity of invention because all three inventions share a special technical feature, a composition comprising an adenoviral vector. Applicant indicates that while the Examiner indicates that Groups 1-3 do not share a special technical feature because the claimed method and composition were known at the time of filing as evidenced by You, 200, Journal of Immunology, 165: 4581-4592 and Bout et al., US Patent 6,913,922, the instant invention is novel and non-obvious and that the Groups share a special technical feature. Applicant indicates that You et al. teach a retroviral vector comprising a nucleic acid sequence encoding a fusion protein comprising a VH leader sequence HBeAg, and a Fc domain administered to dendritic cells. You et al. do not teach using adenoviral vector, used in the instant invention. Bout et al. teach a replication defective adenoviral vector comprising a gene of interest, but do not teach a retrogen cassette (Applicant's response, pages 2-3). In response, as indicated in the Restriction, January 2, 2008, page 3, an artisan would have taken both teachings and combined them to arrive at an adenovirus that is used to administer the construct taught by You et al. You et al. teach that their viral construct was administered to dendritic cells (You et al., abstract). Bout et al. teach that adenoviral constructs can be used to administer to dendritic cells (DCs) and an artisan would have been able to substitute a retroviral vector for an adenoviral one. Applicant indicates that the specification, page

15, lines 12-18 teach because the antigen-presenting pathway to MHC-class I is distinctively different from that of MHC-II, it is difficult for an antigen to be presented to both MHC-I and II by DCs (Applicant's response, page 4). In response, while Applicant indicates the difference of antigen presentation between MHC-I and II, this does not alter the fact that You et al. and Bout et al. provide guidance to arrive at the claimed composition, particularly since You et al. teach administration of the construct to DCs.

Applicant indicates that neither You et al. nor Bout et al. teach or suggest a combination of the adenoviral capsid with the retrogen cassette (Applicant's response, page 4). In response, the art is not required to indicate a teaching or suggestion; it would have been obvious to an artisan to substitute a retroviral vector with that of an adenoviral vector because the art teaches that they are both vehicles of gene delivery and it would have been as obvious to use as much as the other in a method of administering a nucleic acid sequence encoding HBeAg, and a Fc domain.

With regard to Applicant indicating that claims 7-23 are directed to a method using the presently claimed composition and thus, Groups II and II have the same special technical feature as Group 1. Thus, the Groups relate to a single general inventive concept. In response, as discussed above, the art provide guidance to arrive at the composition, Group 1. Because the special technical feature, the composition, was known at the time of filing, the instant inventions lack unity and are thus separated.

Applicant refers to §803 of the MPEP which indicates that restriction/election between two groups of claims is proper when 1) one group of claims is independent or distinct from another group of claims and 2) as "serious burden" exists in examining

both groups (Applicant's response, page 5). In response, §803 is not used in a 371 lack of unity. As such, Applicant's response is not germane to the instant lack of unity.

Applicant indicates that a filing fee for an examination of all the claims in the instant application has been paid. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring Applicants to file divisional applications for each of the groups of claims, the Examiner would be forcing applicants to pay duplicative fees for the non-elected or withdrawn claims (Applicant's response, page 6). In response, fees are not a reason for the Examiner to rejoin inventions.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of Group 1 in the reply filed on January 30, 2008 is acknowledged.

Claims 1-6, drawn to a composition comprising an adenoviral vector, wherein said vector comprises an adenoviral capsid and a nucleic acid molecule comprising a nucleic acid sequence encoding an antigen protein, a leader sequence linked to the N-terminal of said antigen protein, and a cell-binding domain linked to the C-terminal of said antigen protein, are under consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over You et al., 2000, The Journal of Immunology, 165: 4581-4592, previously cited, January 2, 2008, in view of Bout et al., US Patent 6,913,922, patented July 5, 2005, previously cited, January 2, 2008.

You et al. teach a antigen (Ag) presentation strategy that transduces dendritic cells (DC) to produce an Ag for presentation as an exogenous AG to efficiently induce both humoral and cellular immunity (You et al., abstract). You et al. teach a retroviral construct that was used to transduce DCs. The construct comprised a nucleic acid sequence encoding a fusion protein of a VH signal leader sequence, hepatitis B virus (HBV) nucleocapsid protein (HBeAg), and a cell-binding of the Fc fragment of IgG (You et al., page 4581, under "Construction of expression vectors" and Figure 1A).

While You et al. teach retroviral vector, they do not teach adenoviral vector.

Bout et al. teach that adenoviral vectors, particular those comprising a part of Ad35, has an ability to efficiently tranduce DCs (Bout et al., col. 7, lines 10-13). With regard to using adenoviral vectors with Ad11, Bout et al. teach that these vectors are good to use in human applications because the neutralizing activity in human serum that destroys them is low (Bout et al., Example 5).

Because both You et al. and Bout et al. teach the use of retroviral and adenoviral vectors to transduce dendritic cells, it would have been obvious for an artisan to substitute the retroviral vector taught by You et al. with the adenoviral vector taught by Bout et al., in order to arrive at a composition that can be administered to dendritic cells.

Thus, the claims are obvious.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has

been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Art Unit 1632